ORAL ARGUMENT NOT YET SCHEDULED

No. 24-1188 (Consolidated with Nos. 24-1191, 24-1192)

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

AMERICAN WATER WORKS ASSOCIATION, et al.,
Petitioners,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, et al.,
Respondents.

On Petition for Review of a Final Rule of the Environmental Protection Agency,
89 Fed. Reg. 32,532 (Apr. 26, 2024)

PROOF BRIEF OF RESPONDENT-INTERVENORS

Dated: January 17, 2024

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to Circuit Rule 28(a)(1), counsel for Respondent-Intervenors Buxmont Coalition for Safe Water, Clean Cape Fear, Clean Haw River, Concerned Citizens of WMEL Water Authority Grassroots, Environmental Justice Task Force, Fight for Zero, Merrimack Citizens for Clean Water, Newburgh Clean Water Project, and Natural Resources Defense Council submit this certificate as to parties, rulings, and related cases.

A. Parties and Amici

The petitioners, respondents, and intervenors in these consolidated cases are set forth in the brief of American Water Works Association and Association of Metropolitan Water Agencies ("Utility Petitioners") (ECF No. 2078734, "Utility Br."), and in the brief of the National Association of Manufacturers, American Chemistry Council, and the Chemours Company FC, LLC ("Industry Petitioners") (ECF No. 2078734, "Industry Br."). Additionally, as set forth in the brief of Respondents United States Environmental Protection Agency ("EPA") and Acting Administrator Jane Nishida (ECF No. 2091318, "EPA Br."),[1] Chamber of Commerce of the United States is participating as Amicus Curiae for Petitioners (ECF No. 2080190), and the State of Connecticut, Cape Fear River Watch, Center

[1] Acting Administrator Nishida is automatically substituted for her predecessor, former Administrator Micheal Regan. Fed. R. App. P. 43(c)(2).

for Environmental Health, Harper Peterson, Toxic Free North Carolina, and Micheal Watters are participating as Amici Curiae for Respondents (ECF No. 2069131, 2087891). A group of interested scientists also seeks to participate as Amici Curiae for Respondents. (ECF No. 2089133).

B. Rulings Under Review

The agency action under review is EPA's rule entitled "PFAS National Primary Drinking Water Regulation," 89 Fed. Reg. 32,532 (Apr. 26, 2024).

C. Related Cases

The above-captioned case (No. 24-1188) has been consolidated with two additional petitions for review, National Ass'n of Manufacturers, et al. v. EPA, et al. (No. 24-1191) and The Chemours Co. FC, LLC v. EPA, et al. (No. 24-1192). Respondent-Intervenors are not aware of any other related cases within the meaning of Circuit Rule 28(a)(1)(C).

DATED: January 17, 2025

Respectfully submitted,

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RULE 26.1 DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1 and D.C. Circuit Rule 26.1, Respondent-Intervenors state that they are non-profit organizations. They each have no parent corporations and no publicly held corporation owns a 10 percent or greater ownership interest in any of the organizations.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

*Authorities upon which we chiefly rely are marked with an asterisk.

Cases

Statutes

Regulations

Legislative History

Federal Register Notices

State Statutes

Other Authorities

GLOSSARY

ACC	American Chemistry Council
Act or SDWA	Safe Drinking Water Act
AMWA	Association of Metropolitan Water Agencies
AWWA	American Water Works Association
Board	Science Advisory Board
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
Chamber	U.S. Chamber of Commerce
Chemours	The Chemours Company FC, LLC
EPA or the agency	Environmental Protection Agency
Goal	Maximum Contaminant Level Goal
HFPO-DA	Hexafluoropropylene oxide dimer acid
Index PFAS	HFPO-DA, PFBS, PFHxS, and PFNA
Industry Petitioners	NAM, ACC, and Chemours
NAM	National Association of Manufacturers
ng/L	Nanograms per liter (equal to parts per trillion)
OMB	Office of Management and Budget
PFAS	Per- and polyfluoroalkyl substances
PFBS	Perfluorobutane sulfonic acid
PFHpA	Perfluoroheptanoic acid
PFHxS	Perfluorohexane sulfonic acid

PFNA	Perfluorononanoic acid
PFOS	Perfluorooctane sulfonic acid
PFOA	Perfluorooctanoic acid
ppt	Parts per trillion (equal to nanograms per liter)
Rule or Final Rule	PFAS National Primary Drinking Water Regulation, 89 Fed. Reg. 32,532 (Apr. 26, 2024)
Standard	Maximum Contaminant Level
UCMR	Unregulated contaminants monitoring rule
Utility Petitioners	AWWA and AMWA

INTRODUCTION

The Environmental Protection Agency ("EPA")—and water utilities and chemical manufacturers—have known for decades that per- and polyfluoroalkyl substances ("PFAS") are toxic and present in drinking water. EPA's "PFAS National Primary Drinking Water Regulation," 89 Fed. Reg. 32,532 (Apr. 26, 2024), JA-[FR_EPA-HQ-OW-2022-0114-3076_32532] (the "Rule" or "Final Rule") will provide long-overdue relief to communities suffering an epidemic of disease and death linked to these toxic "forever chemicals." Respondent-Intervenors represent some of the communities on the front lines of this crisis.

There are thousands of PFAS chemicals. The Rule regulates just six, for which health hazards and widespread exposures are well established: perfluorooctanoic acid ("PFOA"), perfluorooctane sulfonic acid ("PFOS"), perfluorohexane sulfonic acid ("PFHxS"), perfluorononanoic acid ("PFNA"), hexafluoropropylene oxide dimer acid ("HFPO-DA"), and perfluorobutane sulfonic acid ("PFBS"). But even this targeted, long-anticipated step is a bridge too far for the chemical industry and water utility Petitioners, who seek to put their pecuniary interests ahead of commonsense health protections for hundreds of millions of people.

The Rule reflects rational, well-supported EPA decisions that are consistent with the best available science and the best reading of the Safe Drinking Water Act

(the "Act"). Petitioners' contrary arguments misapprehend the Act, conflate separate statutory requirements, and recycle disagreements with EPA's scientific conclusions that the agency considered and rejected.

Respondent-Intervenors adopt EPA's brief and, consistent with D.C. Circuit Rule 28(d)(2), supplement it as follows.[2]

PERTINENT STATUTES AND REGULATIONS

Pertinent statutes and regulations not provided with Utility Petitioners' and EPA's addenda (ECF Nos. 2078735, 2091319) are provided in the accompanying addendum.

STATEMENT OF THE CASE

I. EPA'S OVERDUE REGULATION OF PFAS IN DRINKING WATER

The Rule is a long overdue step to address a public health crisis that threatens hundreds of millions of people nationwide. More than half the U.S. population—approximately 200 million people—are drinking PFAS-contaminated water. JA-[EPA-HQ-OW-2022-0114-1808_att.1_at_2 & n.2]. EPA estimates that water systems serving as many as 105 million people provide drinking water

[2] Respondent-Intervenors adopt EPA's Statement of Jurisdiction, Statement of the Issues, and Statement of the Standard of Review.

contaminated with PFAS at levels exceeding the Rule's Standards.[3] JA-[FR_32600] (Final Rule).

EPA has been long aware of this crisis. Far from reflecting a "rush[ed]" or "hast[y]" process as Petitioners claim, Utility Br. 2; *accord* Industry Br. 46, the Rule was decades in the making. EPA has known for twenty years or more that PFAS endanger human health. In 2005, EPA issued the largest administrative penalty in its history against DuPont, a member of Petitioner American Chemistry Council, for withholding information about the health risks of PFOA, which DuPont manufactured. *See* Mot. to Intervene of Buxmont Coal. for Safe Water et al. 2 & n.1 (ECF No. 2062232) (citing EPA announcement). State and civil actions against DuPont regarding PFOA contamination commenced as early as 2001 and, in 2006, EPA determined that DuPont's contamination of drinking water with PFOA may present "an imminent and substantial endangerment" to residents near its West Virginia facility. JA-[EPA-HW-OW-2022-0114-1251_2-3].

EPA identified PFOA and PFOS as candidates for regulation under the Safe Drinking Water Act in 2009. JA-[EPA-HQ-OW-2022-0114-0886_51852].[4] The same year, EPA issued provisional drinking water health advisories for PFOA and

[3] This brief uses the same abbreviations as EPA's, including "Goal" for "Maximum Contaminant Level Goal" and "Standard" for "Maximum Contaminant Level."

[4] In 2022, EPA designated all remaining PFAS as candidates for regulation. JA-[FR_32537].

PFOS, which are based on a comprehensive review of the peer-reviewed scientific literature and identify "health-based hazard concentrations above which action should be taken to reduce exposure" in drinking water. EPA, *Provisional Health Advisories for Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonate (PFOS)* 1 n.1 (2009), https://www.epa.gov/sites/default/files/2015-09/documents/pfoa-pfos-provisional.pdf. Beginning in 2013, EPA required nation-wide monitoring for six PFAS: PFOA, PFOS, PFHxS, PFNA, PFBS, and PFHpA. JA-[FR_32537].

EPA conducted updated scientific reviews in 2016 and again in 2022, concluding each time that PFOA and PFOS in drinking water pose health risks at substantially lower concentrations than previously understood. *See* Lifetime Health Advisories for Perfluorooctanoic Acid and Perfluorooctane Sulfonate, 81 Fed. Reg. 33,250, 33,251 (May 25, 2016) (reducing health advisory levels from 400 ppt for PFOA and 200 ppt for PFOS to 70 ppt for PFOA and PFOS combined); Lifetime Drinking Water Health Advisories for Four Perfluoroalkyl Substances, 87 Fed. Reg. 36,848, 36,849 (June 21, 2022) (establishing interim health advisory levels of 0.004 ppt for PFOA and 0.02 ppt for PFOS).

EPA concurrently undertook a years-long process of publishing toxicity assessments for PFAS subject to the Rule, which involve comprehensive review and synthesis of the peer-reviewed literature by EPA scientists, consultation with

other federal scientists, public comment, and external peer review. JA-[EPA-HQ-OW-2022-0114-3080_at_1-7-1-8] (PFOA); JA-[EPA-HQ-OW-2022-0114-3081_at_1-7-1-8] (PFOS); JA-[EPA-HQ-OW-2022-0114-0095_at_v-vi] (PFBS); JA-[EPA-HQ-OW-2022-0114-0102] (HFPO-DA). For PFHxS and PFNA, the Rule relies on the Agency for Toxic Substances and Disease Registry's toxicological profiles, which also underwent extensive peer review and public comment. JA-[FR_32545]; JA-[EPA-HQ-OW-2022-0114-0642_iii, vi-vii].

As EPA and fellow federal agencies progressed slowly through this process of scientific analysis, EPA resisted calls for expeditious regulatory action from communities suffering from severe PFAS contamination. *See*, *e.g.*, Decl. of Jennifer Rawlison ¶ 18; Decl. of Emily Donovan ¶ 16.[5] In some of these communities, including communities where Intervenors' members live, residents have been exposed to PFAS in their drinking water at levels hundreds of times higher than the health-protective Standards EPA ultimately promulgated. *See, e.g.*, JA-[EPA-HQ-OW-2022-0114-1808_att.1_at_3_n.7] (describing PFOA detections of 600 ppt in drinking water in Hoosick Falls, New York—150 times higher than EPA's Standard in the Rule); Decl. of Joanne Stanton ¶ 5 (describing 2015 testing showing that water in Harleysville, PA, "contained some of the highest levels of

[5] The cited declarations accompany the Motion to Intervene of Buxmont Coalition for Safe Water et al., ECF No. 2062232, or NRDC, ECF No. 2062233.

PFAS pollution ever detected" in drinking water); Donovan Decl. ¶ 7; Decl. of Brenda Hampton ¶ 3.

The burden of disease and death associated with this contamination is staggering. While EPA deliberated, people in communities from New Hampshire to Florida to Arizona suffered and died from cancer and other diseases associated with the PFAS in their water. *See*, *e.g.*, Stanton Decl. ¶¶ 8-12, 34 ("Today, there are three-year-olds with kidney cancer in the town where I grew up. My current county has the highest rate of male childhood cancer in Pennsylvania."); Decl. of Jessica Merricks ¶ 9 (describing neighbors' experiences of "miscarriages and multiple cancers within a household"); Decl. of Laurene Allen ¶ 20; Decl. of Linda Shosie ¶ 6; Decl. of Stel. Bailey ¶ 3; Decl. of Randall Dail ¶ 9.

Brenda Hampton, for example, has been diagnosed with kidney disease—which is linked to PFOA and PFOS exposure—as have her mother, "grandfather, grandmother, two siblings, and several nieces, in addition to many friends and neighbors" in Lawrence County, Alabama, where industrial facilities contaminated the drinking water with PFOA, PFOS, and other PFAS. Hampton Decl. ¶¶ 2-5. In 2016, as Ms. Hampton was learning that the overwhelming incidence of kidney disease, cancer, miscarriages, and stillbirths in her community may be caused by

PFAS exposure, her water system warned customers to stop drinking or cooking with their tap water because of high levels of PFOA and PFOS.[6]

Emily Donovan's drinking water comes from North Carolina's Cape Fear River, a watershed with PFAS levels "among the highest in the nation." Donovan Decl. ¶¶ 1, 7. The levels of PFOA in Ms. Donovan's blood are at or above the 95th percentile level nationwide. *Id.* ¶ 10. Indeed, she and her husband have multiple PFAS in their blood, including two manufactured by Petitioner Chemours. *Id.* Many children and young adults in Ms. Donovan's community have kidney cancer, and her "own inner circle of friends and neighbors is filled with loved ones suffering from the trauma of cancer treatments, benign tumors, and terminal diagnoses." *Id.*

Building on decades of investigation by EPA and the broader scientific community into the health risks of PFAS-contaminated drinking water, the Rule is now poised to deliver long-awaited relief to these communities and others across the country. "Once fully implemented, the EPA estimates that the rule will prevent thousands of deaths and reduce tens of thousands of serious PFAS-attributable illnesses," JA-[FR_32532] (Final Rule), providing the protection the Act requires,

[6] Dennis Pillion, *100,000 North Alabama Customers Advised Not to Drink Water Due to Chemical Contamination*, AL.com (June 2, 2016), https://www.al.com/news/2016/06/100000_north_alabama_customers.html.

see City of Portland v. EPA, 507 F.3d 706, 709 (D.C. Cir. 2007) (affirming that the Act "requires EPA to protect the public from … drinking water contaminants").

Importantly, for millions of people this relief can come *only* from EPA because many states prohibit their state agencies from establishing drinking water standards more stringent than EPA's or constrain that authority. *See*, *e.g.*, Ariz. Rev. Stat. Ann. § 49-104(A)(16) (prohibiting state standards more stringent than corresponding federal standards); Miss. Code Ann. § 41-26-6(1) (similar); Fla. Stat. Ann. § 403.804(2) (establishing prerequisites to adoption of state standards that exceed federal requirements); Utah Code Ann. § 19-4-105 (same); Tenn. Code Ann. § 4-5-226(k) (providing for legislative termination of state standards that are more stringent than federal standards); Ky. Rev. Stat. Ann. § 13A.245 (requiring particularized justification for state standards that are more stringent than federal standards).[7]

SUMMARY OF ARGUMENT

Petitioners are not entitled to any relief for their claim that EPA erred by concurrently promulgating regulatory determinations and Standards for the "Index PFAS," *i.e.*, HFPO-DA, PFBS, PFHxS, and PFNA. Petitioners offer no evidence or

[7] In addition, Wyoming, the District of Columbia, and most Tribal Nations lack delegated authority to implement the Act, leaving their populations dependent upon EPA Standards. EPA, *Safe Drinking Water Act (SDWA) Resources and FAQs*, https://echo.epa.gov/help/sdwa-faqs#Q24 (last updated Dec. 5, 2024).

argument that they were prejudiced by EPA's procedure; accordingly, any procedural error was harmless.

Petitioners' substantive challenges to EPA's regulatory determinations lack merit. EPA compiled ample evidence that HFPO-DA, PFNA, and Index PFAS mixtures occur or likely will occur in water systems across the nation at levels that may threaten human health. And EPA relied on robust evidence that, in mixtures, the Index PFAS may have additive adverse health effects.

EPA's Standard-setting decisions were rational and consistent with the Act. Petitioners' arguments rest largely on conflating two separate decisions: (1) EPA's determinations that each Standard is as close as "feasible" to the applicable Goal, and (2) EPA's determination that the Standards' benefits justify their costs. EPA properly set the PFOA and PFOS Standards as close to the relevant Goal as feasible; its judgment that the benefits of doing so justify the costs played no role in determining the Standards. EPA's decision to use a Hazard Index Standard comports with the Act and EPA's prior practices, and it is supported by an extensive record showing dose-additive effects and real-world circumstances that necessitate regulation of Index PFAS mixtures. EPA satisfied its obligation to consult with its Science Advisory Board regarding the Standards by requesting Board feedback on key scientific issues.

Even assuming the Act allows Petitioners to challenge EPA's determination that the Standards' benefits justify their costs, Petitioners' flyspecking fails to show that EPA acted arbitrarily, either in its underlying Economic Analysis or consequent justification determination. EPA's consideration of nonquantifiable regulatory benefits was consistent with the Act, established economic-analysis practices, and the record. Likewise, EPA rationally conducted the Economic Analysis to avoid double-counting or omitting the Standards' costs or benefits, employing a comprehensive approach that is consistent with the Act and EPA practice.

The Court should deny the petitions. Petitioners' claims lack merit and, even if the Court finds any claim has merit, it should provide targeted relief that leaves intact all severable aspects of the Rule.

ARGUMENT

I. EPA'S DETERMINATIONS TO REGULATE THE INDEX PFAS ARE CONSISTENT WITH THE ACT AND SUPPORTED BY THE RECORD

As EPA explains, the Act's capacious definition of "contaminant" encompasses mixtures and groups of related chemicals in drinking water and empowers EPA to regulate mixtures of the Index PFAS. EPA Br. 25-29. Furthermore, EPA's concurrent publication of its preliminary determinations to regulate the Index PFAS and proposed Standards comports with the Act and, even

assuming it did not, any error was harmless. Finally, EPA's determinations to regulate the Index PFAS are well supported by the record.[8]

A. Any Alleged Error in EPA's Regulatory Procedure Was Harmless

EPA has explained why the Act permits simultaneous publication of preliminary regulatory determinations and proposed Standards. EPA Br. 29-37. However, even assuming *arguendo* that EPA's process deviated from the Act's requirements, any error was harmless. Petitioners have not demonstrated any prejudice from the simultaneous processes and have waived their opportunity to do so.

"The APA requires petitioners to show prejudice from an agency procedural violation." *City of Waukesha v. EPA*, 320 F.3d 228, 246 (D.C. Cir. 2003); *see* 5 U.S.C. § 706 ("[D]ue account shall be taken of the rule of prejudicial error."). Petitioners' arguments and evidence do not address, much less demonstrate, any prejudice from EPA's regulatory procedure. Utility Br. 15-32; Industry Br. 12-13, 34-37. Petitioners argue that the Act requires separate comment periods for preliminary regulatory determinations and proposed Standards. Utility Br. 32; Industry Br. 37. But they have not shown that "they would have submitted additional, different comments" had there been another comment period. *City of*

[8] Petitioners do not challenge EPA's regulatory determinations for PFOA, PFOS, or PFHxS.

Waukesha, 320 F.3d at 246. Petitioners (and their *amicus*) submitted hundreds of pages of comments on the proposed Rule. *See* Utility Br. SA4-5 (AWWA), SA14 (AMWA); Industry Br. 52 (Chemours), Add.B4 (NAM), Add.B9-10 (ACC); Chamber Br. 2. For example, Petitioner AWWA asserts that its comments were based on "an extensive review of EPA's legal and policy justifications, health risk reduction and cost analysis, and associated materials" and included "a cost modeling report … ; a compilation of case studies … ; and an analysis of EPA's toxicology analyses." Utility Br. SA4-5.[9]

It is not evident that Petitioners were harmed by the lack of a second comment period, and "[a] party forfeits an argument by failing to raise it in [its] opening brief." *Al-Tamimi v. Adelson*, 916 F.3d 1, 6 (D.C. Cir. 2019). Petitioners cannot newly argue prejudice on reply. *Cf. Union of Concerned Scientists v. U.S. Dep't of Energy*, 998 F.3d 926, 931 (D.C. Cir. 2021) (holding that injury argument for standing purposes was forfeited when raised for the first time in reply).

[9] Petitioners' assertion that EPA was required to consult the Board regarding the Index PFAS regulatory determinations, Industry Br. 4, 34, misconstrues the Act and cannot be the basis for any purported prejudice. Petitioners conflate EPA's process for listing unregulated contaminants for consideration, which includes Board consultation, 42 U.S.C. § 300g-1(b)(1)(B)(i)(I), with EPA's preliminary determination to regulate, which does not, *id.* § 300g-1(b)(1)(B)(ii)(I). Listing a contaminant, and the attendant Board consultation, is not a prerequisite for regulatory determinations. *Id.* § 300g-1(b)(1)(B)(ii)(III).

Petitioners are not entitled to relief for this claim because any error was harmless. *See* EPA Br. 36-38.[10]

B. EPA Properly Determined That the Index PFAS Occur, Individually and in Mixtures, with a Frequency and at Levels of Public Health Concern

To regulate the Index PFAS, EPA was required to determine that each regulated contaminant "is known to occur *or there is a substantial likelihood* that the contaminant will occur in public water systems with a frequency and at levels of public health concern." 42 U.S.C. § 300g-1(b)(1)(A)(ii) (emphasis added). "[T]he statute does not require, and the EPA does not use [] minimum or one-size-fits-all occurrence thresholds (for either frequency or precise level) for regulatory determinations." JA-[RTC_EPA-HQ-OW-2022-0114-3077_3-30] (Response to Comments). Instead, "it is a contaminant-specific decision which involves consideration of a number of factors." JA-[FR_32552] (Final Rule) (cleaned up); *see* EPA Br. 39-40.

To evaluate the occurrence of the Index PFAS, EPA assembled data collected under its third unregulated contaminants monitoring rule ("UCMR 3") and state-collected data to generate "one of the most robust occurrence datasets ever." JA-

[10] Even if the Court found a prejudicial procedural error, the appropriate relief is narrow. Petitioners argue that EPA's Standard-setting for the Index PFAS was premature so, at most, only the Index PFAS Standards should be remanded, leaving intact the regulatory determinations for the Index PFAS and the Standards for PFOA and PFOS. *See* EPA Br. 120.

[FR_32553] (Final Rule). The UCMR 3 data included sampling for PFHxS, PFNA, and PFBS. *Id.* The "state data were primarily gathered after the UCMR 3 using improved analytical methods that could measure more PFAS at lower concentrations" and included data for HFPO-DA. *Id.* Although EPA appropriately considered all of the state data, *see* EPA Br. 42, EPA's evaluation of state data "focused … on the non-targeted or non-site specific (*i.e.*, monitoring not conducted specifically in areas of known or potential contamination) monitoring efforts from 19 states" that were "likely to be more representative of general occurrence" and "less likely to potentially over-represent concentrations at locations of known or suspected contamination." JA-[FR_32553] (Final Rule).

1. HFPO-DA Occurrence

EPA rationally concluded that HFPO-DA occurrence data support regulation because "HFPO-DA continues to be actively produced and used throughout the U.S., it currently occurs at levels above its [health reference level], and it occurs within geographically diverse areas of the country demonstrating it is not a local or regional issue only." JA-[FR_32557] (Final Rule); *see* EPA Br. 45-48.

Available data identified "at least 75 [water] systems in 13 states serving more than 2.5 million people that reported any concentration of HFPO-DA, and at least 13 systems in 5 states within different geographic regions of the country serving a population of 227,000 people with reported concentrations above the

[health reference level] of 10 ng/L." JA-[FR_32557] (Final Rule). EPA projected that, nationwide, "HFPO-DA would be detectable in over 320 [public water systems] serving 9.9 million people" and "would be detected above the [health reference level] in 42 systems with at least 495,000 people exposed." *Id.*

EPA also reasonably "anticipate[d] that contamination will continue, if not increase, due to disposal and breakdown [of HFPO-DA] in the environment." JA-[FR_32557] (Final Rule). For example, between 2020-2022, EPA's Toxics Release Inventory recorded environmental releases of thousands of pounds of HFPO-DA and its ammonium salt, JA-[Occurrence_Support_EPA-HQ-OW-2022-0114-3086_197-98] (Occurrence Support), from Chemours facilities in North Carolina, New Jersey, and West Virginia and non-Chemours facilities in Alabama, Texas, and South Carolina.[11] These data may be underinclusive due to the Inventory's reporting threshold and exemptions. JA-[Occurrence_Support_197] (Occurrence Support).

Although EPA's occurrence dataset for HFPO-DA was more than sufficient to support EPA's regulatory determination, it likely underestimated existing

[11] EPA, *TRI Explorer*, https://enviro.epa.gov/triexplorer/tri_release.trends (last accessed Jan. 16, 2025) (record document EPA-HQ-OW-2022-0114-3150, cited at JA-[Occurrence_Support_197-98] (Occurrence Support) as "USEPA, 2023b"); *select* Geographic Location: "All of United States," Industry: "All Industries," Chemical: "Hexafluoropropylene oxide dimer acid (listed 2020)," Data Set: "Select 2022 Dataset (released October 2023)," *then click* "Generate Report," *then click* Year "2022."

contamination. First, it did not include state-gathered data from all states where EPA's Toxics Release Inventory documented HFPO-DA releases, including New Jersey, Texas, and West Virginia. *See* JA-[Occurrence_Support_201-04] (Occurrence Support). Second, the reporting thresholds in some states were substantially higher than EPA's 10 ppt Standard for HFPO-DA, such as in Ohio, Oregon, New York, and Massachusetts. *Id.* Thus, the available data do not reflect HFPO-DA water contamination in these states below applicable reporting thresholds.

Petitioners' assertions that HFPO-DA is only a concern for communities near Chemours facilities in North Carolina, West Virginia, and New Jersey are unavailing. *Contra* Industry Br. 45, 51, Add.B14; Utility Br. 47-48. Petitioners offer no explanation for HFPO-DA detections in states far from those facilities, including Alabama, Colorado, Iowa, Massachusetts, Michigan, New Hampshire, New York, South Carolina, Vermont, and Virginia. JA-[Occurrence_Support_205-207]; EPA Br. 47. Utility Petitioners' hypothesis that the Ohio River transports HFPO-DA from West Virginia to Kentucky communities hundreds of river-miles downstream is hardly comforting. Utility Br. 47-48; JA-[EPA-HQ-OW-2022-0114-0431_21] (map showing HFPO-DA in Kentucky water systems hundreds of miles downstream from West Virginia border). Indeed, Petitioners' theory suggests that HFPO-DA may continue spreading into communities in the ten states along the

Ohio and Mississippi Rivers that are downstream of Chemours' West Virginia facility. This only reinforces EPA's conclusions that HFPO-DA "is not a local or regional issue only" and "a national level regulation is necessary." JA-[FR_32555, 32557] (Final Rule); *contra* Utility Br. 47-48.

2. PFNA Occurrence

EPA's conclusion that PFNA occurrence supports regulation was also well founded. *See* EPA Br. 54-56. Available data showed "at least 480 systems in 19 states serving more than 8.4 million people that reported any concentration of PFNA, and at least 52 systems in 12 states within different geographic regions serving a population of 177,000 people with reported concentrations above the [health reference level] of 10 ng/L." JA-[FR_32556] (Final Rule). EPA projected that, nationwide, PFNA is likely "detectable in over 2,300 [systems] serving 24.9 million people," and that "PFNA would be detected above the [health reference level] in 228 systems with 830,000 people exposed." *Id.*

Petitioners' theory that PFNA is a problem only in the northeast is inconsistent with the occurrence data. *Contra* Utility Br. 50-51. PFNA also has been detected above the health reference level of 10 ng/L in Alabama, Colorado, Michigan, North Carolina, Ohio, South Dakota, Texas, and Washington, and at lower levels in Arizona, California, Illinois, Indiana, Kentucky, South Carolina, and Wisconsin. JA-[Occurrence_Support_174-77, 189-90].

3. Occurrence of Index PFAS Mixtures

EPA determined to regulate through the Hazard Index Standard "mixtures that include at least two of PFHxS, PFNA, HFPO-DA, and PFBS," JA-[FR_32589] (Final Rule), so the occurrence analysis for Index PFAS mixtures focuses on co-occurrence of two or more of these PFAS. After analyzing the occurrence data for the regulated PFAS, both as a group and as pairs of individual chemicals, EPA found that the Index PFAS "are demonstrated to generally co-occur with each other." JA-[FR_32593] (Final Rule). More specifically, "where either three or four Hazard Index PFAS were monitored … two or more of the Hazard Index PFAS were reported in approximately 12.1 percent of monitored [water] systems." JA-[FR_32558] (Final Rule). Extrapolating nationwide from these data, EPA found that two or more of the Index PFAS likely "co-occur in about 8,000" public water systems. *Id.*

Moreover, the Index PFAS co-occur at levels exceeding the Hazard Index Standard. Available data show that "across 21 states there are at least 211 [public water systems] serving approximately 4.7 million people with results above a Hazard Index of 1 for mixtures including two or more of the Hazard Index PFAS." JA-[FR_32558] (Final Rule). Extrapolating nationwide, EPA estimated that 300 to 700 water systems serving a population of 9 to 18 million people likely exceed the Hazard Index Standard. JA-[Occurrence_Support_250, Ex. 10-5] (Occurrence

Support). Based on the totality of its analysis—including "the environmental persistence of these PFAS, their presence in consumer products and continued use, the findings of both the pairwise and groupwise co-occurrence analyses, and demonstration of combinations of Hazard Index PFAS mixtures exceeding the Hazard Index of 1"—EPA rationally concluded that "there is a substantial likelihood that combinations of the four Hazard Index PFAS in mixtures co-occur at frequencies and levels of public health concern." JA-[FR_32558] (Final Rule); *see* EPA Br. 56-61. EPA is entitled to "an extreme degree of deference" to this evaluation of "scientific data within its technical expertise." *City of Waukesha*, 320 F.3d at 247 (cleaned up).

C. EPA Reasonably Determined the Index PFAS May Have Adverse Health Effects

EPA reasonably determined that the Index PFAS "may have an adverse effect on … health," sufficient to justify a determination to regulate them as a mixture. 42 U.S.C. § 300g-1(b)(1)(A)(i). EPA found "substantial evidence that PFHxS, PFNA, HFPO-DA, and PFBS act in a dose additive manner, that these four PFAS elicit similar health effects, and that exposure to mixtures of these PFAS may have adverse health effects." JA-[FR_32550] (Final Rule). "Dose additivity means that when two or more of the component chemicals … exist in one mixture, the risk of adverse health effects following exposure to the mixture is equal to the sum of the individual doses or concentrations scaled for potency," such that

"exposure to these PFAS, at doses that individually would not likely result in adverse health effects, when combined in a mixture may pose health risks." *Id.*

EPA thoroughly considered and rationally rejected comments that argued there was insufficient evidence that the Index PFAS "elicit similar adverse health effects." JA-[FR_32551] (Final Rule); *see* JA-[RTC_4-367–4-378] (Response to Comments). "Numerous published studies … support a dose-additive mixture assessment approach for PFAS because … observed responses to exposure to PFAS … are consistent with modeled predictions of dose additivity." JA-[FR_32550] (Final Rule). And, since 2021, "new studies from the EPA and others have published robust evidence of combined toxicity of PFAS in mixtures, corroborating and confirming earlier findings." *Id.* (collecting citations). Specifically, EPA concluded that the Index PFAS "are documented to affect at least five (5) of the same health outcomes for this evaluation: lipids, developmental, immune, endocrine, and hematologic," and "significantly affect at least eight (8) of the same major health effect domains: body weight, respiratory, hepatic, renal, endocrine, immunological, reproductive, and developmental." JA-[FR_32551] (Final Rule); JA-[RTC_4-371–4-378] (Response to Comments).

Contrary to Petitioners' arguments, *contra* Utility Br. 37-39; Industry Br. 42-43, "[t]he fact that the toxicity reference values … for the four [Index] PFAS are based on different health endpoints does not mean that the four PFAS are not

toxicologically similar; rather, it means that based on the *available* data, the most sensitive endpoint *currently known* is different for each of these PFAS," JA-[RTC_4-428] (Response to Comments) (emphasis added). To protect against *all* adverse health effects, the "Hazard Index approach uses the most health-protective toxicity reference value available for each of the four PFAS." *Id.*

Petitioners' argument that EPA needs evidence of specific adverse health effects caused by combinations of Index PFAS at concentrations exceeding the Hazard Index Standard but not any individual Standard, Industry Br. 42-43, is a red herring. The Act requires only a finding that Index PFAS mixtures "*may* have an adverse [health] effect," which is not an onerous standard. 42 U.S.C. § 300g-1(b)(1)(A)(i) (emphasis added). EPA explained that "[s]tudies with PFAS … support the health-protective conclusion that toxicologically similar chemicals (*i.e.*, those that elicit similar observed adverse effects following individual exposure, even if at different exposure levels) should be assumed to act in a dose-additive manner when present in a mixture unless data demonstrate otherwise." JA-[RTC_4-368] (Response to Comments). Accordingly, EPA concluded that "exposure to [the Index] PFAS, at doses that individually would not likely result in

adverse health effects, when combined in a mixture may pose health risks." *Id.* EPA's conclusion satisfied its statutory burden.[12]

II. PETITIONERS' CHALLENGES TO THE FEASIBILITY OF THE PFOS AND PFOA STANDARDS LACK MERIT

The PFOS and PFOA Standards are "feasible" as defined by the Act: capable of being implemented "with the use of the best technology … which the Administrator finds … [is] available (taking cost into consideration)." 42 U.S.C. § 300g-1(b)(4)(D); EPA Br. 66-72. Indeed, Petitioners rightly decline to challenge EPA's bottom-line conclusion that affordable technologies are available to meet the Standards—including granular activated carbon, which the Act itself dictates is *per se* feasible for treating synthetic organic chemicals like PFAS. 42 U.S.C. § 300g-1(b)(4)(D).

Instead, Industry Petitioners jumble together criticisms of EPA's cost-benefit analysis—which, as explained *infra*, section IV.A, is separate from and had no bearing on EPA's determination of what Standard is as close to the Goal as feasible——with unpersuasive arguments that EPA inadequately considered

[12] Petitioners' argument also misconstrues the meaning of Goals and Standards. EPA must set each Goal "at the level at which *no known or anticipated adverse effects on the health of persons occur* and *which allows an adequate margin of safety*." 42 U.S.C. § 300g-1(b)(4)(A) (emphasis added). A Standard must be "as close to the [Goal] as is feasible." *Id.* § 300g-1(b)(4)(B). If there was evidence of adverse health effects at exposures equal to the Goal, that would indicate that the Goal was insufficiently protective, without any margin of safety.

certain practical aspects of feasibility or weaker standards preferred by Petitioners. Industry Br. 14-30; *cf.* EPA Br. 66 n.10.

As EPA explains, it addressed thoroughly Petitioners' concerns about the practicability of meeting the Standards. EPA Br. 69-72. Additionally, although "feasible" means affordable for large public water systems, *id*. at 67, EPA also assessed costs for smaller systems; reduced monitoring costs by permitting use of existing data; and determined, consistent with EPA guidance, that treatment technologies are affordable and available for small systems, *see* JA-[FR_32627-29] (Final Rule); JA-[RTC_2-96] (Response to Comments). Further, while feasibility does not hinge on ratepayer affordability, EPA identified multiple resources and strategies to address this concern, JA-[RTC_2-96] (Response to Comments), including billions of dollars for compliance assistance from the Bipartisan Infrastructure Law, JA-[FR_32538, 32639, 32727] (Final Rule). Water utilities also are securing billions of dollars in settlement funds in litigation against PFAS manufacturers.[13] *See* JA-[EPA-HQ-OW-2022-0114-1723_att.1_3-4].

[13] For example, shortly before EPA finalized the Rule, water utilities settled with PFAS manufacturer 3M Company for more than 10 billion dollars, on top of a previous 1.18 billion-dollar settlement with manufacturers including Petitioner Chemours, and claims against additional manufacturers remained. Sharon Udasin, *Federal Court Finalizes 'Forever Chemical' Settlement Between 3M, Water Systems for Billions*, The Hill (Apr. 2, 2024), https://thehill.com/policy/energy-environment/4569757-federal-court-finalizes-forever-chemical-settlement-3m-water-systems/; *see generally Aqueous Film-Forming Foam (AFFF) Products*

Finally, EPA adequately considered alternative Standards. EPA Br. 72-74. In arguing to the contrary, Industry Petitioners improperly invoke the requirements for EPA's cost-benefit analysis to attack EPA's determination of what Standards are feasible. *See* Industry Br. 27-28 (citing 42 U.S.C. § 300g-1(b)(3)(C)(i)(III)-(IV)). Moreover, while Industry Petitioners correctly observe that agencies must consider "significant and viable" alternatives, *id.* at 28 (quotation omitted), their preferred alternatives would violate EPA's statutory obligation to set Standards as close to the Goals as feasible and therefore are not viable, *see* 42 U.S.C. § 300g-1(b)(4)(B).[14]

III. THE HAZARD INDEX STANDARD IS CONSISTENT WITH THE ACT AND SUPPORTED BY THE RECORD

The Hazard Index Standard is consistent with the Act's requirements and with prior Standards governing mixtures or groups of related chemicals in drinking water. It is also consistent with EPA's use of a hazard index to determine risks and resultant cleanup requirements under the Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA"), and it is necessary to address the health risks from exposure to multiple Index PFAS.

Liability Litigation (MDL 2873), Public Water System Settlements, https://www.pfaswatersettlement.com/ (last accessed Jan. 13, 2025).

[14] Contrary to Petitioners' claim, Industry Br. 29, EPA addressed critiques that no meaningful difference exists between Standards of 4.0 and 5.0 ppt, explaining that because any PFOA or PFOS exposure increases cancer risk, the risk between 4.0 and 5.0 ppt increases linearly, JA-[RTC_5-193] (Response to Comments).

A. The Hazard Index Standard Is Consistent with the Act and EPA Practice

The Hazard Index Standard satisfies EPA's duty to promulgate regulations limiting "each contaminant" EPA determines to regulate. 42 U.S.C. § 300g-1(b)(1)(E). *Contra* Industry Br. 31. This requirement obligates EPA to ensure that every contaminant for which the agency makes a positive regulatory determination is covered by a Standard or treatment technique—an obligation EPA can satisfy with a Standard covering multiple chemicals in a group or mixture. Indeed, Congress envisioned "a comprehensive approach to standard setting" under the Act that "combine[s] … group-wide regulations with regulations for certain sub-groups and specific contaminants within [a] group of substances." H.R. Rep. No. 93-1185, at 10-11 (1974), 1974 U.S.C.C.A.N. 6454, 6463-64.

As EPA explains, there is ample precedent for Standards that, like the Hazard Index Standard, (1) apply to mixtures or groups of related chemicals; and (2) provide that the allowable level of each chemical is not a fixed concentration, but rather depends upon the level(s) of the other chemical(s) subject to the Standard in sampled drinking water. For example, EPA's rule for radionuclides includes a combined Standard of 5 PicoCuries per liter for two distinct radioactive substances, radium-226 and radium-228. 40 C.F.R. § 141.66(b). Water systems determine compliance by adding their measured values for radium-226 and radium-228, such that a relatively higher value for one is permissible when the

value for the other is lower. *Id*. This Court upheld the radionuclides rule in *City of Waukesha v. EPA*, 320 F.3d 228 (D.C. Cir. 2003) (no party challenged the combined nature of the radium Standard).

Similarly, EPA's regulation for disinfection byproducts includes combined Standards for total trihalomethanes—measured as "the sum of measured concentrations of" four chemicals—and for a group of five haloacetic acids—measured as "the sum of measured concentrations of" the five haloacetic acids. Disinfectants and Disinfection Byproducts, 63 Fed. Reg. 69,390, 69,408 (Dec. 16, 1998); *see also* 40 C.F.R. §§ 141.64(b) (codifying Standards), 141.2 (defining covered chemicals). Utility Petitioners endorsed these multi-chemical Standards in regulatory negotiations.[15]

Thus, there is nothing novel about requiring water systems to determine compliance with a Standard using a "mathematical equation" and Utility Petitioners are incorrect that the Hazard Index Standard "bears no resemblance to the concentration-based levels that EPA has, until now, used under the Act." Utility Br. 35. To the contrary, EPA's consistent interpretation that the Act authorizes

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[15] *See* Microbial/Disinfection Byproducts (M-DBP) Fed. Advisory Comm., *Stage 2 M-DBP Agreement in Principle* 2-4 & attach. A (2000), https://www.epa.gov/sites/default/files/2015-11/documents/stage_2_m-dbp_agreement_in_principle.pdf; EPA, *Microbial/Disinfection Byproducts Federal Advisory Committee Agreement in Principle*, https://archive.epa.gov/water/archive/web/html/mdbpagre.html (last updated Mar. 6, 2012) (see section 2.1 and signatories).

Standards that (1) cover multiple related chemicals and (2) provide that the allowable level of each chemical varies depending on the level(s) of the other(s) supports EPA's position here. *See Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 388 (2024) (affirming that the "consistency" of an agency's "pronouncements" supports giving greater weight to its interpretation (quoting *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944))).

Indeed, the only difference between the Hazard Index Standard and the prior multi-chemical Standards discussed above is that the Hazard Index is more sophisticated because it accounts for variation in the potency of the Index PFAS, *i.e.*, the exposure level at which each chemical presents health risks. It accomplishes this by requiring water systems to divide the measured concentration of each Index PFAS by that chemical's unique health risk level (the "health-based water concentration" or HBWC), which scales the measured concentration for potency before combining the concentrations for all Index PFAS in a sample. JA-[FR_32578] (Final Rule); *see* JA-[RTC_4-418–4-419] (Response to Comments).

EPA did not have sufficient data to support this approach when promulgating prior multi-chemical Standards; as a result, the prior Standards require water systems to simply sum the measured concentrations of each covered chemical without scaling for potency. *See*, *e.g.*, 63 Fed. Reg. at 69,409 (rejecting critique that the disinfection byproducts rule improperly failed to "take into account

differing health effects and potencies" of covered chemicals and explaining that multi-chemical Standard for haloacetic acids was necessary, *inter alia*, because of "inadequate health data to characterize the potential health risks for several of the [haloacetic acids]"); Radionuclides, 65 Fed. Reg. 76,708, 76,720 (Dec. 7, 2000) (acknowledging that radioactive contaminants covered by combined Standards "differ from one another in ways that determine their harmfulness").

The Hazard Index Standard takes advantage of the abundant data available for the Index PFAS to account for each chemical's unique potency. Accordingly, it represents an advancement in EPA's development of multi-chemical Standards grounded in the best available science and the statutory mandate to promulgate Standards as close as feasible to the level at which adverse health effects are not anticipated and which allows for an adequate margin of safety. 42 U.S.C. § 300g-1(b)(4)(A)-(B).

B. Petitioners Misconstrue EPA's Prior Uses of a Hazard Index

As EPA explained, "[t]he Hazard Index is an approach based on dose additivity that has been validated and used by the EPA to assess chemical mixtures in several contexts," including to determine cleanup requirements under CERCLA. JA-[FR_32568, 32570] (Final Rule). Petitioners misconstrue that application of the Hazard Index as a "screening/comparison tool[]." Utility Br. 33; *id.* at 36-37.

Contrary to Petitioners' characterization, EPA utilizes a hazard index in its CERCLA risk assessments to "assess the overall potential for noncarcinogenic effects posed by more than one chemical" at contaminated sites and identify cleanup levels required to meet CERCLA's mandate of protecting human health from uncontrolled hazardous substance releases. JA-[EPA-HQ-OW-2022-0114-0891_1-1, 8-11–8-13] (CERCLA guidance); *see* JA-[FR_32570] (Final Rule); *see also, e.g.*, EPA, *Record of Decision, Lower Passaic River Study Area, OU4* 23-24 (2021), https://semspub.epa.gov/work/02/630399.pdf (explaining that EPA uses hazard index to characterize risks from multiple contaminants at CERCLA sites, "identif[y] contamination with concentrations that exceed acceptable levels," and determine which contaminants "will require remediation at the site"); *id.* at 30, 36 (explaining that EPA's selected response action "is necessary to protect the public health or welfare" from, *inter alia*, "non-cancer health hazards … [that] are above acceptable levels" established by hazard indices for fish and crab consumption). Like its use under CERCLA, EPA's Hazard Index Standard identifies exposures to multiple chemicals in drinking water that may pose additive non-cancer health risks. *E.g.*, JA-[FR_32542-43] (Final Rule).

C. The Hazard Index Standard Is Well Supported by the Record

EPA rationally determined that Index PFAS mixtures require regulation and that a Hazard Index Standard is the best mechanism to do so. Petitioners' contrary

arguments do not justify second-guessing EPA's conclusions. *See Nat. Res. Def. Council v. EPA*, 824 F.2d 1211, 1216 (D.C. Cir. 1987) (explaining that the Court does not "undertake comparative evaluations" of scientific evidence and "aims only to discern whether the agency's evaluation was rational").

As discussed in section I.C, *supra*, EPA reasonably determined that the Index PFAS cause similar, dose-additive, adverse health effects. *See also* EPA Br. 61-65, 78-79. In addition to misstating the Science Advisory Board's recommendations, *see id.* at 79, Petitioners erroneously argue that an independent expert panel's conclusions undermine EPA's decision to group the Index PFAS, Utility Br. 38, and ignore EPA's evaluation of the panel's findings. EPA considered and rejected Petitioners' contentions, concluding that "[t]he Anderson et al. (2022) panel agree[d] that grouping PFAS that affect the 'same target organ/tissue/system' is supportable" and that the four Index PFAS do indeed "affect many of the same target organs/tissues/systems." JA-[RTC_4-426] (Response to Comments).[16]

EPA also considered and reasonably rejected other approaches to regulating Index PFAS mixtures. For example, EPA concluded that "[a] whole-mixture

[16] Petitioners' argument that EPA could use a Hazard Index to regulate any combination of co-occurring contaminants, Utility Br. 39-40; Industry Br. 43-44, is a hypothetical concern unmoored from the record. The Index PFAS fit squarely within the type of group regulation that Congress envisioned and EPA has repeatedly implemented. *See supra* section III.A; EPA Br. 27-29. The required determinations in 42 U.S.C. § 300g-1(b)(1)(A)(i)-(iii) provide the limiting principles for grouping chemicals into regulated mixtures.

approach … is not possible because it would entail developing a single toxicity value … for one specific mixture of PFHxS, PFNA, HFPO-DA, and PFBS with defined proportions of each PFAS." JA-[FR_32542] (Final Rule). However, "[t]oxicity studies are typically conducted with only one test substance to isolate that particular substance's effects on the test organisms," and "[t]here are no known whole-mixture studies for PFHxS, PFNA, HFPO-DA, and PFBS." *Id.* Moreover, "even if they were available," a toxicity reference value derived from such a study "would only be directly applicable to that specific mixture." *Id.* Instead, EPA rationally concluded that "a more flexible approach" is "necessary"—one that considers the potential for the four PFAS to co-occur in different combinations and at different concentrations across time and space. *Id.*

The rationality of EPA's approach is borne out by real-world circumstances. As discussed in section I.B.3, *supra*, EPA estimated that hundreds of water systems nationwide, serving millions of people, exceed the Hazard Index Standard. Indeed, Intervenors' members are exposed to various combinations of Index PFAS and will benefit from regulation of these mixtures. *See, e.g.*, Shosie Decl. ¶ 5 ("PFOA, PFOS, PFBS, PFHxS, PFNA and PFHpA have all been detected in my water."); Allen Decl. ¶ 7 ("[I]n addition to PFOA and PFOS, we have at least 21 other PFAS in our groundwater."); Vandal Decl. ¶¶ 12-13 & tbls.1-2 (compiling water system reports showing Index PFAS mixtures in intervenor's members' water in multiple

states). The Index PFAS co-occur in drinking water, may not exceed the individual Standards, and cannot be regulated solely under state law. *See, e.g.*, Shosie Decl. ¶¶ 5, 16-17; Ariz. Rev. Stat. Ann. § 49-104(A)(16) (prohibiting state standards more stringent than federal standards).

"Agency determinations based upon highly complex and technical matters are entitled to great deference." *Midwest Ozone Grp. v. EPA*, 61 F.4th 187, 192 (D.C. Cir. 2023) (cleaned up). Petitioners' disagreements with EPA's thoroughly reasoned decisions regarding the Hazard Index Standard do not warrant relief.

D. EPA Satisfied the Statutory Requirement to Consult Its Science Advisory Board

EPA complied with the statutory requirement to consult the Board. The Act does not require EPA to obtain Board review of each Goal and Standard. EPA Br. 92-94. *Contra* Industry Br. 39. It simply directs EPA to "request comments" from the Board "prior to proposal of" a Goal or Standard, 42 U.S.C. § 300g-1(e), and EPA did just that, EPA Br. 14-16, 62, 92-94. The Court should reject Petitioners' request that it "assume that Congress has omitted from its adopted text requirements that it nonetheless intends to apply." *See Jama v. Immigr. & Customs Enf't*, 543 U.S. 335, 341 (2005).

Petitioners' contrary argument relies on the flawed theory that "a" is always singular. Industry Br. 39. As discussed in section V.B.2, *infra*, that reading of section 300g-1 is wrong and ignores applicable statutory construction principles.

Moreover, Congress was clear that the extent of Board review "shall, under no circumstances, be used to delay final promulgation" of a Rule. 42 U.S.C. § 300g-1(e); EPA Br. 94-95. Here, EPA rationally requested Board input on a focused set of issues, including "critical issues" related to deriving Goals and Standards for PFAS mixtures "that had not yet been subject to peer review where [Board] commentary would be most valuable." JA-[RTC_4-427] (Response to Comments). By contrast, the toxicity evaluations for the four Index PFAS "had been externally peer reviewed prior to the [Board] review."[17] *Id.* EPA's approach fulfilled its statutory obligation and ensured that its engagement with the Board did not delay the Rule's promulgation.

IV. EPA PROPERLY CONSIDERED COSTS AND BENEFITS

As EPA explains, Petitioners misrepresent the role of cost-benefit analysis under the Act. EPA Br. 95-99. The Act requires EPA to consider the benefits and/or costs of proposed Standards in two distinct ways: First, EPA's determination of whether a Standard is feasible must take cost into consideration. 42 U.S.C. § 300g-1(b)(4)(B), (D). Second, EPA must publish a determination of whether a proposed

[17] Contrary to amicus Chamber of Commerce's argument that EPA skirted Board and peer review by relying on PFHxS and PFNA toxicity values from the Agency for Toxic Substances and Disease Registry, Chamber Br. 23-26, EPA explained in detail why these values were the "best available, peer reviewed science" and refuted the Chamber's contentions, JA-[RTC_4-507-4-509, 4-521-4-522] (Response to Comments).

Standard's benefits justify its costs (the "justification determination"). *Id.* § 300g-1(b)(4)(C). Both determinations are subject to deferential arbitrary and capricious review. *See* 5 U.S.C. § 706(2)(A); 42 U.S.C. § 300g-1(b)(6)(D).

Petitioners improperly conflate these requirements and fail to explain how asserted flaws in EPA's assessment of regulatory costs or benefits justify vacatur of any part of the Rule—let alone the entire Rule. Industry Br. 14-15 (arguing purported cost-benefit errors "alone call[] for vacatur of the entire Rule"); Utility Br. 53-55 (arguing that cost-benefit analysis cannot provide an adequate basis for EPA's justification determination so "[t]he Rule must therefore be vacated and remanded"). While Petitioners disagree with various inputs and findings in the analyses supporting these determinations, Petitioners fail to establish that the alleged flaws render either determination arbitrary and capricious. *See* EPA Br. 114-119.

A. Petitioners Overstate the Role of EPA's Economic Analysis in Setting Standards

As EPA explains, the "health risk reduction and cost analysis" the Act requires—which EPA documented in its Economic Analysis, JA-[Economic_Analysis_EPA-HQ-OW-2022-0114-3084_1-1]—does not dictate the stringency of the Standards EPA adopts. 42 U.S.C. § 300g-1(b)(3)(C); *see* EPA Br. 95-97. Rather than basing its selection of Standards on this cost-benefit analysis, EPA is required to set Standards "as close to the [Goals] as is feasible," 42

U.S.C. § 300g-1(b)(4)(B), subject to limited discretionary authority discussed below that does not apply here. Instead, the health risk reduction and cost analysis informs EPA's *separate* "determination as to whether the benefits of [a proposed Standard] justify, or do not justify, the costs," which EPA must publish for comment with a proposed rule. *Id*. § 300g-1(b)(4)(C).

Congress explained that the justification determination requires EPA to "determine whether the benefits of a standard 'justify' (rather than 'exceed' or 'outweigh') the costs." S. Rep. No. 104-169, at 33 (1995). "The Administrator is not required to demonstrate that the dollar value of the benefits are greater (or lesser) than the dollar value of the costs. All costs and benefits, both quantifiable and nonquantifiable, must be considered when making [justification] determinations." *Id.*; *see* 42 U.S.C. § 300g-1(b)(3)(C)(i) (establishing analytical requirements).

The justification determination and supporting analysis serve two purposes. First, they increase public transparency. *See, e.g.,* S. Rep. No. 104-169, at 2 ("[A] public record must be created to educate the American people about the risks they face from a particular contaminant, and the costs to regulate it."). Second, if EPA determines that a proposed Standard's benefits do not justify the costs of compliance, EPA has discretion to consider a Standard that is not as close to the Goal as feasible. 42 U.S.C. § 300g-1(b)(6)(A); EPA Br. 96-97. But this limited

discretionary authority is not a mandate to set "cost-effective rules." Chamber Br. 7-8. To the contrary, EPA has discretion to "set a [Standard] as close to the … [G]oal as feasible, even if the Administrator determines that the benefits of the [Standard] at this level do not justify the costs." S. Rep. No. 104-169, at 33.[18]

Even assuming that EPA's justification determination is reviewable, *see* EPA Br. 99-102 (explaining why it is not reviewable here), and even if Petitioners could establish that the determination was arbitrary and capricious (it was not, as discussed below), Petitioners fail to explain how an invalid justification determination would warrant vacatur of the Rule. *See* Industry Br. 14-15; Utility Br. 53-55. None of the Standards are based on EPA's cost-benefit analysis—they are properly set as close to the relevant Goal as feasible—and additional aspects of the Rule (*e.g.*, the Goals) required no analysis of costs or benefits. Further, the Act provides limited relief for an arbitrary and capricious justification determination that is proportional to the determination's limited purposes: the court may "set aside" *the determination.* 42 U.S.C. § 300g-1(b)(6)(D). Petitioners never explain how their criticisms of the cost-benefit analysis supporting EPA's justification determination warrant the broad relief they seek; the bare assertion that supposed

[18] Industry Petitioners falsely assert that EPA may "elect not to promulgate a regulation" altogether if it determines that a proposed Standard's benefits do not justify the costs. Industry Br. 6. Petitioners cite no support for that assertion and there is none.

"errors" in EPA's cost-benefit analysis "call[] for vacatur of the entire Rule," Industry Br. 15; *see* Utility Br. 55, does not suffice. *See N.Y. Rehab. Care Mgmt., LLC v. NLRB*, 506 F.3d 1070, 1076 (D.C. Cir. 2007) ("It is not enough merely to mention a possible argument in the most skeletal way, leaving the court to do counsel's work." (quotation omitted)).

B. Petitioners Have Failed to Establish that EPA's Justification Determination Was Arbitrary and Capricious

Petitioners' critiques of the Economic Analysis lack merit and provide no basis for overturning EPA's justification determination. In a standalone judicial review provision specific to the justification determination, Congress provided that the Court may overturn that determination only if Petitioners establish that it is arbitrary and capricious, 42 U.S.C. § 300g-1(b)(6)(D), *i.e.*, not "reasoned, principled, and based upon the record," *Env't Def. Fund v. FERC*, 2 F.4th 953, 968 (D.C. Cir. 2021). The court does "not reweigh the evidence or second-guess technical judgments," but rather is "limited to determining whether EPA made a rational judgment." *Mississippi v. EPA*, 744 F.3d 1334, 1346, 1348 (D.C. Cir. 2013).

Congress made clear that EPA has sole discretion to determine what regulatory costs are "worth it" based on anticipated benefits and that a court is not to second-guess inputs to EPA's underlying Economic Analysis. In enacting the

judicial review provision specific to justification determinations, 42 U.S.C. § 300g-1(b)(6)(D), Congress explained that its

> objective is to prevent litigation challenging the values that the Administrator implicitly assigns to preventing death and disease when the Administrator determines that the benefits of a rule do or do not justify the costs. A Federal court action … is not the appropriate forum in which to decide the precise value of a human life or the costs that are appropriately incurred for precautionary and preventive public health measures.

S. Rep. No. 104-169, at 37. Where, as here, Congress intended that "administrative judgment play[] a key role, … this court must proceed with particular caution." *Nat. Res. Def. Council*, 824 F.2d at 1217 (cleaned up).

Petitioners fail to establish that EPA's justification determination should be set aside because it is arbitrary and capricious. Instead, they unconvincingly argue that the underlying Economic Analysis is deficient because EPA supposedly: (1) overstated the Rule's nonquantifiable benefits, (2) underestimated compliance costs,[19] and (3) impermissibly combined cost-benefit analyses for multiple Standards. Intervenors supplement EPA's counterarguments on points (1) and (3).

[19] EPA explains why it properly analyzed costs, EPA Br. 114-19, and amicus's arguments based on its own cost study are unavailing. *Contra* Chamber Br. 12-13. EPA considered and rejected the Chamber's cost analyses. JA-[RTC_13-124-13-126].

1. EPA Properly Assessed the Rule's Nonquantifiable Benefits

Industry Petitioners err in asserting that EPA improperly considered as "nonquantifiable … benefits," 42 U.S.C. § 300g-1(b)(3)(C)(i)(I), health benefits of the Rule that are theoretically capable of quantification but for which EPA lacked sufficient record evidence to support quantification. Industry Br. 20-23.

As EPA notes, the definition of "nonquantifiable" on which Industry Petitioners rely, *i.e.*, "not capable of being quantified," does not support their argument. EPA Br. 108. Something may be "not capable of being quantified" because a lack of available data makes it so in particular circumstances.

Further, Industry Petitioners' argument contravenes basic principles of regulatory cost-benefit analysis. Within that discipline, there is not a category of benefits that intrinsically are amenable to quantification and another category that are not. Instead, as EPA's economic analysis guidelines explain, "[i]deally, all benefits and costs of a regulation would be expressed in monetary terms, but this is almost never possible because of data gaps, unquantifiable uncertainties, and other challenges … . If important benefit or cost categories cannot be expressed quantitatively, they should be discussed qualitatively." JA-[EPA-HQ-OW-2022-0114-1299_11-3]. Similarly, U.S. Office of Management and Budget ("OMB") guidance for regulatory analysis explains that regulatory benefits may be difficult to quantify or monetize because "difficulty in collecting the relevant data or

conducting the relevant experiment prevents measurement. For example, science might not have progressed to the point where it is possible to quantify the harm done by some pollutant … .” JA-[OMB_Guidance_EPA-HQ-OW-2022-0114-3169_44-45]. When agencies “determine that it is not possible or appropriate, *given the state of the evidence*, to quantify or monetize certain effects, [they] should carefully identify and assess the non-monetized and unquantified benefits and costs.” JA-[OMB-Guidance_44] (emphasis added).[20]

EPA’s assessment of nonquantifiable benefits is also well supported by the record. *See* EPA Br. 110. EPA’s review of the best available science concluded that

> PFAS exposure is associated with a wide range of adverse health effects, including reproductive effects such as decreased fertility; increased high blood pressure in pregnant women; developmental effects or delays in children, including low birth weight, accelerated puberty, bone variations, or behavioral changes; increased risk of some cancers, including prostate, kidney, and testicular cancers; reduced ability of the body’s immune system to fight infections, including reduced vaccine response; interference with the body’s natural hormones; and increased cholesterol levels and/or risk of obesity.

[20] Indeed, even the benefit categories Industry Petitioners claim are properly deemed “nonquantifiable” because they supposedly are inherently incapable of quantification can be quantified using metrics such as willingness-to-pay. *Compare* Industry Br. 21-22 (arguing EPA may properly consider as a nonquantifiable benefit avoidance of painful or uncomfortable health effects over effects that are not painful or uncomfortable), *with* JA-[OMB_Guidance_48] (OMB guidance explaining that “pain and suffering and other quality of life effects” of regulation can be quantified and monetized using willingness-to-pay).

JA-[FR_32712] (Final Rule); *see also* JA-[Economic_Analysis_6-25-6-31] (Economic Analysis summarizing evidence). Yet EPA resisted commenters' calls to quantify additional benefits of the Rule that have strong support in the scientific and economic literature, determining that the evidence was sufficiently robust to quantify benefits from reducing only *three* adverse health effects associated with PFOA and PFOS. JA-[FR_32712, 32715, 32717] (Final Rule); *see* JA-[RTC_ 13-511, 13-472-13-473] (Response to Comments). This reflects a conservative approach that erred on the side of "significantly understat[ing] the benefits of the rule." JA-[RTC_13-511] (Response to Comments).

2. EPA's Grouping of Standards for Cost-Benefit Analysis Accords with the Act and EPA Practice

The Act does not require separate cost-benefit analyses for "each" Standard. *Contra* Industry Br. 15-16. Petitioners' argument that cost-benefit provisions that refer to "a" or "the" Standard are always singular ignores the principle that, "in expounding a statute, [courts] must not be guided by a single sentence or member of a sentence, but look to the provisions of the whole law." *Del. Dep't of Nat. Res. & Env't Control v. EPA*, 895 F.3d 90, 97 (D.C. Cir. 2018) (cleaned up). Because the Act explicitly allows EPA to promulgate rules containing multiple Standards, the cost-benefit provisions must be interpreted to account for such rules. *See* EPA Br. 113 (discussing 42 U.S.C. § 300f(1)). Petitioners' theory fails to do so, and further disregards the principle that "words importing the singular include and apply to

several … things," "unless the context indicates otherwise." 1 U.S.C. § 1; *see also* Antonin Scalia & Bryan A. Garner, *Reading Law* 129-31 (2012) (explaining that interpreting singular words to encompass plural is common sense and best drafting practice). Instead, Petitioners "impart inappropriate significance to the use of the singular versus the plural." *Sweet Home Chapter of Cmtys. for a Great Or. v. Babbitt*, 1 F.3d 1, 6-7 (D.C. Cir. 1993) (rejecting arguments that references to "a" or "any" species required species-by-species actions), *opinion modified on reh'g on other grounds,* 17 F.3d 1463 (D.C. Cir. 1994), *rev'd on other grounds,* 515 U.S. 687 (1995); *see also In re Rail Freight Fuel Surcharge Antitrust Litig., MDL No. 1869*, 34 F.4th 1, 10 (D.C. Cir. 2022) ("[U]se of the singular phrase 'an interline movement' should be interpreted to include multiple movements.").

The phrases "a … level" or "the … level" in 42 U.S.C. § 300g-1(b)(3)(C)(i) and (b)(4)(C) are best read as singular or plural based on whether the relevant rule contains one Standard or multiple Standards. This is the only interpretation that both addresses the single- and multi-Standard rules the Act authorizes and gives these phrases a consistent meaning when applied to rules containing multiple Standards. For example, section 300g-1(b)(3)(C)(i) states:

> "When proposing any national primary drinking water regulation that includes *a maximum contaminant level*, the Administrator shall, with respect to *a maximum contaminant level* that is being considered" conduct specified cost-benefit analyses.

(emphases added). Here, Petitioners' interpretation requires the same phrase to have different meanings in the same sentence, interpreting the first "a … level" to encompass plural "levels" but interpreting the second "a … level" as "each level" to read as follows:

> "When proposing any national primary drinking water regulation that includes [] maximum contaminant level[*s*], the Administrator shall, with respect to [*each*] maximum contaminant level that is being considered" conduct specified cost-benefit analyses. *Id.* (emphases added).

It is more faithful to the statute's language and more internally consistent to read both uses of "a … level" simply to encompass "levels."

Further, regarding the PFOA and PFOS Standards specifically, combining cost-benefit analyses was the only rational approach given EPA's statutory obligation to propose Standards for both chemicals and their tendency to co-occur. *See* EPA Br. 111-12, 114. PFOA and PFOS co-occurred in 68 percent of the 3,374 water systems that detected either chemical. *See* JA-[Occurrence_Support_244, Ex. 9-13] (Occurrence Support) (last row showing 2,304 systems reported both, 729 reported only PFOA, and 341 reported only PFOS). Even the Black and Veatch study on which Petitioners argue EPA should have relied, *see* Utility Br. 54,

analyzed the costs of PFOA and PFOS Standards together, JA-[EPA-HQ-OW-2022-0114-1759-att.3_31, A-5].[21]

EPA's approach also follows best practices for regulatory cost-benefit analysis, *see, e.g.*, JA-[EPA-HQ-OW-2022-0114-0502_18] (OMB 2023 Circular No. A-4) (regulatory analysis "should discuss the anticipated benefits and costs of the selected regulatory option and reasonable alternatives"), and prior EPA practice. For example, in EPA's two rules regulating disinfection byproducts—which, like the PFAS Rule, include multiple Standards—EPA conducted cost-benefit analyses for each regulatory alternative, not each Standard. 63 Fed. Reg. at 69,434, 69,456; Stage 2 Disinfectants and Disinfection Byproducts Rule, 71 Fed. Reg. 388, 441-42 (Jan. 4, 2006); JA-[EPA-HQ-OW-2022-0114-3603_4-3-4-7] (Economic Analysis for Stage 2 Disinfectants and Disinfection Byproducts Rule). In the "Stage 2" disinfection byproducts rule, EPA established one Standard for multiple trihalomethanes and a second Standard for multiple haloacetic acids. Like the regulated PFAS, those groups of contaminants have similar health effects and physical and chemical properties, co-occur in drinking water, and are treated effectively by the same technology. JA-[FR_32702-03]; 71 Fed. Reg. at 394-406.

[21] EPA reasonably rejected the Black and Veatch cost analysis, EPA Br. 115-16, and Intervenors' independent analysis confirmed that EPA's cost estimate was "robust" while assumptions in the Black & Veatch report overestimated costs by billions of dollars, JA-[EPA-HQ-OW-2022-0114-1808_att.4_6] (Betanzo Report).

As here, the Economic Analysis included cost-benefit analyses for four regulatory alternatives, each of which contained multiple Standards, and did not include separate analyses for individual Standards within each alternative. JA-[EPA-HQ-OW-2022-0114-3603_4-1-4-7] (noting also that Petitioners AWWA and AMWA participated in developing these regulatory alternatives). Similarly, EPA calculated benefits from reducing multiple co-occurring contaminants subject to a treatment technique under EPA's groundwater rule. EPA, *Economic Analysis for Final Ground Water Rule*, at ES-9 (2006), https://www.regulations.gov/document/EPA-HQ-OW-2018-0780-0214. Accordingly, this Court should afford *Skidmore* deference to EPA's interpretation that the Act does not require separate cost-benefit analyses for each individual Standard. *See Orton Motor, Inc. v. U.S. Dep't of Health & Hum. Servs.*, 884 F.3d 1205, 1211, 1214 (D.C. Cir. 2018) (holding that agency's consistent application of position weighs in favor of adopting agency interpretation).

Ultimately, Petitioners' cost-benefit analysis arguments fail because EPA's justification determination does not, as Petitioners claim, depend upon the Standards' "expected quantifiable net benefit[s]." Industry Br. 18; *see also id.* at 17 (claiming incorrectly that the Index PFAS Standards "are not justified" unless their quantified benefits exceed their quantified costs). As explained *supra*, section IV.A, the Act also requires EPA to consider nonquantifiable benefits and costs and

gives EPA discretion to determine that the Standards' benefits justify their costs even if quantified costs exceed quantified benefits. Petitioners' recycling of misguided arguments about the purpose and methodology for EPA's justification determination to attack EPA's approach to the cost-benefit analysis for the Rule's multiple Standards is unavailing.

V. REMEDY

If the Court finds any legal defect in the Rule, the remedy should be narrowly tailored to the specific error, leaving all severable portions of the Rule intact. EPA Br. 120-22. It would "exceed the statutory scope of review for a court to set aside an entire rule where only a part is invalid, and where the remaining portion may sensibly be given independent life." *Cath. Soc. Serv. v. Shalala*, 12 F.3d 1123, 1128 (D.C. Cir. 1994). "Severability turns on agency intent," *Nasdaq Stock Mkt. LLC v. SEC*, 38 F.4th 1126, 1144 (D.C. Cir. 2022), and here EPA made clear that it intended for the Rule to be severable, JA-[FR_32731-32] (Final Rule). Petitioners' bid for vacatur of the entire Rule is illogical because multiple severable aspects of the Rule are unchallenged, *see* EPA Br. 121, and Petitioners fail to explain how—even if any or all the challenges they do raise had merit—that would justify the relief they seek.

CONCLUSION

The Court should deny the petitions for review.

DATED: January 17, 2025

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I certify that this document complies with Fed. R. App. P. 32(a)(5) and (6) because it uses 14-point Times New Roman, a proportionally spaced font, with 1-inch margins.

I also certify that this document complies with the Court's Briefing Order (ECF No. 2072754) because according to Microsoft Word's count, it has 9,100 words, excluding the parts exempted under Fed. R. App. P. 32(f) and D.C. Cir. R. 32(e)(1).

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CERTIFICATE OF SERVICE

I certify that on January 17, 2025, I electronically filed the foregoing document and its addendum with the Court's CM/ECF system, which will serve each party's counsel of record.

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